GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:1789
ANSWERED ON:07.03.2013
MARGIN ON COMMON DRUGS
Das Shri Khagen

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the study conducted by the Ministry of Corporate Affairs revealed that there is 500 per cent margin on 21 common drugs manufactured by the drug companies in the country;

(b) if so, the details thereof;

(c) the reasons for selling those drugs at 500 per cent margin in spite of National Pharmaceutical Pricing Authority's Regulation that profit margin should not be more than 100 per cent; and

(d) the action taken or proposed to be taken by the Government against such companies?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) to (d) The Ministry of Corporate Affairs, based on the study and analysis of Cost Audit Reports, has brought out a list of formulations where the concerned formulators were charging very high profit margins over their legitimate costs in respect of the formulations based on following drugs:

(i) Amlodipine

(ii) Azithromycin

(iii) Ciprofloxacin

(iv) Metformin

There are broadly two categories of drugs under Drugs (Price & Control) Order, 1995 (DPCO, 1995) for the purpose of price fixation / revision and monitoring. These are scheduled drugs (drugs under price control) and non-scheduled drugs. National Pharmaceutical Pricing Authority (NPPA) fixes / revises prices of 74 scheduled bulk drugs and related formulations from time to time as per the provisions of DPCO, 1995. Under the provisions of the DPCO, 1995, the prices of 74 bulk drugs and the formulations containing any of these scheduled drugs are controlled. No one is authorized to sell any scheduled drug / formulation at a price higher than the price fixed by NPPA. The NPPA fixes / revises the prices of scheduled formulations from time to time as per formula given in Para 7 of DPCO,1995.

As per Para 7 of DPCO, 1995, MAPE of 100% is allowed. MAPE (Maximum allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer form the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed One hundred per cent for indigenously manufactured Scheduled formulations.

Provided that in the case of imported formulation, the landed cost form the basis for fixing its price alongwith such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty per cent of the landed cost.

In respect of drugs not covered under the Drugs (Prices Control) Order, 1995 i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government / NPPA. NPPA has no control on the launch price of the non scheduled formulations. NPPA, however, regularly examines the movement in prices of non-scheduled formulations. The monthly reports of IMS Health and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% in a period of one year on moving basis is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest.

Out of the four drugs mentioned above, Ciprofloxacin is the only scheduled drug under DPCO, 1995. So far as this drug is concerned, the prices of bulk drugs Ciprofloxacin and related formulations could not be revised as the matter is sub-judice. NPPA is also aware of the lower market price of the bulk drug Ciprofloxacin than the notified price under DPCO, 1995. In case of Ciprofloxacin based formulations, NPPA had initiated actions for overcharging against the formulator. However, some of the defaulting major formulators

have gone to the Court and due to a stay granted in the writ petition filed by M/s. Ranbaxy in Bombay High Court, price fixation / revision for Ciprofloxacin is affected. Further, NPPA is also restrained to take coercive action for the recovery of the overcharged amount from M/s. Ranbaxy due to the said case presently lying sub-judice in High Court of Bombay.

The remaining three drugs, i.e. Amlodipine, Metformin and Azithromycin are non scheduled formulations.

Further, the formulations based on Ciprfloxacin, Amlodipine, Metformin and Azithromycin have been examined by NPPA based on the IMS Health data for the Feb'12 − Feb'11. It has been observed that in no product/pack, increase is beyond 10% per annum having regard to the laid down parameters.

Based on monitoring of prices of non-scheduled formulations, NPPA has fixed prices in case of 30 formulation packs under para 10(b) and companies have reduced price voluntarily in case of 65 formulation packs since inception of NPPA in August, 1997. Thus in all, prices of 95 packs of non-scheduled drugs have got reduced as a result of the intervention of NPPA.

In order to ensure compliance of the notified ceiling price, NPPA calls for the control samples of the subsequent batches and the price list of the companies in respect of the formulations where the companies are found to have overcharged. To ensure that companies adhere to the prices fixed by NPPA, the State Drug Controllers are sensitized and asked to forward the cases relating to non-compliance of the notified price. As a part of continuous market surveillance, NPPA also procures samples of various scheduled formulations to check the compliance of the notified ceiling price by the companies.

On the basis of the complaints registered by individuals / NGOs, reports received from the State Drug Controllers and the samples purchased by NPPA from different parts of the country, compliance of the prices fixed / notified by the NPPA is regularly monitored and ensured. Price list submitted by the company in Form V is scrutinized for the purpose. In case a company is found selling any scheduled formulation at a price higher than that notified/ approved by the NPPA / Government, action is taken against such company as per the provision of DPCO,1995 for recovery of the overcharged amount.